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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/737,144	12/15/2003	Su Il Yum	DURE-050	6360

31498 7590 09/14/2010

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1613	

MAIL DATE	DELIVERY MODE
09/14/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/737,144	**Applicant(s)** YUM ET AL.	
	Examiner BLESSING M. FUBARA	**Art Unit** 1613	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 20 August 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Blessing M. Fubara/
Primary Examiner, Art Unit 1613

Continuation of 11. does NOT place the application in condition for allowance because: The rejection that the original specification does not envision network former from 1-8.6 weight percent in claim 80 is maintained because the specification at paragraph [0075]of the published application as filed envisions a network former "from about 1% to about 8.6%" which is not the same as from 1-8.6%. (please note that claim 81 which depends on claim 80 should have been included in the rejection.

Applicant argues on page 5 that the rejection on record makes improper assumptions and the examiner is unable to respond to what improper assumptions that have been made without knowing what the improper assumptions are.

On page 5 of the remarks applicant has also stated that the claimed invention has unique and beneficial characteristic and that applicant has carried out series of experiments to show the beneficial characteristics recited in the claims. However, the applicant has not named those beneficial characteristics in the remarks.

On page 6 of the remarks, applicant disagrees with the examiner's analysis that the composition producing the effect in the cited paragraphs is different from that claimed. The examiner did not say that the unexpected results cited by applicant in paragraphs [0018], [0080], [0082], [0084], [0116]-[0119], [0132]-[0135], [0013], [0014], [0015] as showing that the instant formulation exhibits unexpected and surprising results over currently known formulations is "not relevant." What the examiner said in the office action of 6/17/2010 on pages 9 and 10, paragraphs 29-35 is reproduced here below:

---29. A) [0018] talks about the advantage of reduced extraction of the formulation of drug/HVCLM/CAB/rheology/modifier. But such an advantage is produced by specific composition that is not the same as that claimed in claim 1. Further also, the formulation of Tipton contains SAIB, DRUG, CAP, EL and the suggestion to include fatty acid ester.

30. [0080] describes adjusting the ratio of the ingredients of the formulation and that such optimized formulation provides non-obvious formulation rheology. But in this case, the specification at this paragraph [0080] does not say what the comparison is.

31. [0082] describes kinetic of SAIB/oxycodone. However, claim 1 is not directed SAIB/oxycodone and there are no amounts of the SAIB and oxycodone for the composition for which the kinetics is generated. Also, Tipton describes formulation of SAIB and drug.

32. [0084] is a capsule while claim 1 is not a capsule. Therefore, the scope of the composition in [0084] is different from the scope of claim 1.

33. B) [0116]-[0119] is directed to studying gelcaps of oxycodone, one is commercial product of 80 mg oxycodone and the other is one of SAIB:ethyl lactate:IPM:CAB at a ratio of 65:27:3:5 and at 12 mg/kg, the finding is that the commercial product exhibited large initial burst release while the SAIB containing oxycodone formulation does not present a burst release. The data presented in paragraphs [0116]-[0119] does not represent the claimed formulation in that the formulation used to obtain the data is a gelcap having SAIB:ethyl lactate:IPM:CAB at a ratio of 65:27:3:5 and at 12 mg/kg which is not the claimed composition (see claim 1). Therefore, the formulation used to collect the data presented in paragraphs [0116]-[0119] is not commensurate in scope with the claimed formulation.

34. C) [0132]-[0135] compares 9 mg oxycodone formulations containing SAIB/CAB/EL and commercial oxycontin formulation. However, the 9 mg oxycodone formulation containing is not the same scope as claim 1; for example, claim 1 is generic to any drug and Tipton teaches various compositions comprising drug/CAB/SAIB/EL and additional component. None of the claims recite oxycodone.

35. D) [0013]-[0015] compares oxycodone formulation with the specific commercial oxycotinin commercial tablets. However, the claims are not directed to oxycodone and the claims have not recited the specific compositions that provide the unexpected results.---The findings were very clearly analyzed paragraph by paragraph.

On page 6, last paragraph bridging page 7, applicant argues that the office failed to make the proper analysis and provide rational basis as to why one would combine certain specific elements of Tipton, that, it is only by hindsight reconstruction that the office arrived at the claimed invention. The examiner disagrees. Prima facie case of obviousness was clearly laid out in the office action of 6/17/2010 and the examiner fully responded to applicant's arguments in paragraphs 20 through 51. No hindsight reasoning was employed and it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See In re McLaughlin, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the present case, the Tipton art renders obvious the claimed composition.

On pages 7-12, applicant argues that the claimed composition provides long term delivery between 1-20 hours; that failure to provide persuasive reasoning has been found by KSR to support findings of non-obviousness; in all these pages, applicant argues that the claimed composition have been shown in the specification to have unexpected results. The examiner disagrees with the arguments, a) a composition providing long term delivery of 1-20 hours is the characteristic of the composition; b) the office action provided clear reasoning as to why the claimed invention is obvious over Tipton; c) the unexpected results applicant refers to were clearly and exhaustive analyzed in the office action of 6/17/2010 and reproduced here above. For example, paragraphs [0018] and [0080] do not describe any specific composition in terms of amounts of the various components that when combined provides the unexpected results over what is known in the art. This finding is supported by applicant's own specification at paragraph [0116]-[0119] where specific compositions are disclosed. But these compositions are not the claimed compositions in terms of the specific concentrations of the composition components of the composition. The only amount recited in claim 1 is for SAIB in a wide range of 30-90%; claim 1 does not recite amounts for the rheology modifier or network former or solvent or drug. The examiner hopes that this explanation may help clarify why the claimed composition and what composition applicant deems provides the unexpected results are not the same.